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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,662	01/24/2002	John Baird	P84-US4	9661

20988 7590 08/04/2003  
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EXAMINER

MAYES, LAURIE A

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 08/04/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/053,662

Applicant(s)

BAIRD ET AL.

Examiner

Laurie Mayes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-11, 15-18 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12, 14 and 19 is/are rejected.
- 7) ☒ Claim(s) 13 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☒ Interview Summary (PTO-413) Paper No(s) 9.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION*****Election/Restrictions***

Applicant's election with traverse of Group III, claims 12-14 and 19 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the polynucleotide of Group I encodes the protein of Group II and Groups III and IV are methods of using the peptide and polynucleotide. This is not found persuasive because the peptide and polynucleotide have different structures and functions as the polynucleotide may encode a protein and the protein may be used in assays. As the polynucleotide may encode a protein and the protein may be used in assays, the polynucleotide and protein thus have additional uses other than in a method of diagnosing JEB. Further, the polynucleotide and nucleic acid constructs are classified in class 536, subclass 22.1 and class 435, subclass 69.1 and the patent database contains over 9,000 US patents while a search for laminin in Group II involves over 7,500 patents. The processes process of Group II is classified in class 435, subclass 6 with over 10,500 patents while the method of Group IV, classified in class 436, subclass 15, involves a search of over 150 additional patents. These inventions are distinct and have acquired a separate status in the art as shown by their different classification and searches required for each.

The requirement is still deemed proper and is therefore made FINAL.

***Specification***

The use of the trademark QIAQUICK KIT (p. 9, line 40) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

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Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

***Information Disclosure Statement***

The listing of references in the specification (p. 14-15) is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Tryggvason et al. (US 5,660,982). Tryggvason et al. teach a method of diagnosing epidermis bullosa (col. 7, lines 20-25) in a horse comprising the steps of obtaining a biological sample from a preborn foal (col. 8, lines 34-35) (present claim 19), isolating nucleic acid and amplifying laminin g2-encoding nucleic acid using appropriate primers (see Ex. 2, cols. 7-9) and analyzing it to identify the presence of mutated nucleic acid wherein the nucleic acid has a cytosine insert at position 1368 (see SEQ ID NO: 12 and copy of sequence alignment), indicating the diagnosis

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of epidermis bullosa (present claim 12). Tryggvason et al. teach all of the elements of claims 12 and 19 and these claims are anticipated under 35 U.S.C. 102(b).

### ***Claim Objections***

Claim 13 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12, 14 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tryggvason et al. in view of Gjerde et al. (US 6,265,168). Tryggvason et al. teach a method of diagnosing epidermis bullosa (col. 7, lines 20-25) in a horse comprising the steps of obtaining a biological sample from a preborn foal (col. 8, lines 34-35) (present claim 19), isolating nucleic acid and amplifying laminin g2-encoding nucleic acid using appropriate primers (see Ex. 2, cols. 7-9) and analyzing it to identify the presence of mutated nucleic acid wherein the nucleic acid has a cytosine insert at position 1368 (see SEQ ID NO: 12 and copy of sequence alignment), indicating the diagnosis of epidermis bullosa (present claim 12). Tryggvason et al do not teach a method wherein the amplified nucleic acid is chromatographically analyzed to identify the heterozygous presence of the mutated laminin g2-encoding nucleic acid.

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Gjerde et al. teach a method of chromatographic analysis to identify the heterozygous presence of a variant nucleic acid (col. 34, lines 63-67 and col. 35, lines 1-8) (present claim 14). Given the success of chromatographic analysis to detect a variant nucleic acid, it would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to use chromatography to detect the variant laminin g2-encoding nucleic acid taught by Tryggvason et al. Thus, the claimed invention was prima facie obvious to make and use at the time the claimed invention was made.

***Conclusion***

**Claims 12, 13, 14 and 19 are rejected. Claim 13 is objected to.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Mayes whose telephone number is (703) 605-1208. The examiner can normally be reached on Monday through Friday from 9 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.



Laurie Mayes  
Patent Examiner  
Art Unit 1653  
July 31, 2003



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